

### **REMARKS/ARGUMENTS**

By this Amendment, claim 26 is amended to correct a grammatical error. Claims 21-47 are pending.

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

#### **Amendments to the Claims and Support for Amendment**

Independent claims 21 and 45, and dependent claim 31 have been amended by the February 5, 2008 Amendment to more clearly specify that the active substance comprised in the tablet is “*in a form of coated microcrystals or coated microgranules*”. Support for this limitation can be found in previously presented versions of claim 21, claim 31 and claim 45, which recited a tablet comprising “*coated microcrystals or microgranules of an active substance*”. Support for this amendment can also be found throughout the specification as originally filed (see, for example, page 1, lines 29-30, as well as all the Examples of the patent application). The language of the amended claims more clearly distinguishes the claimed tablet (and claimed process) from the prior art. In particular, the new language more specifically highlights the fact that a coating envelops the active substance.

In the Advisory Action mailed March 18, 2008, it is stated that the Examiner originally interpreted the limitation “coated microcrystals or microgranules” to mean coated microcrystals and microgranules which may or may not be coated. It is further mentioned that this broad interpretation did not present problems with respect to written description matter or with respect to enablement. This, therefore, implies that, since the beginning of the prosecution, the claims have been examined considering both alternatives: *i.e.*, (a) an active substance in a form of coated microcrystals or *uncoated* microgranules, and (b) an active substance in a form of coated microcrystals or *coated* microgranules. Accordingly, Applicant respectfully submits that the present claim amendments, which limit the claims to alternative (b), cannot introduce issues that would require further search and consideration.

Applicant would also like to point out that the claim limitation “*active substance in a form of coated microcrystals or coated microgranules*” is found as such (in French) in the claims

of the PCT application (PCT/FR00/00495) of which the present application is the U.S. National Stage. In the PCT application, both claim 1 (which recites a tablet) and claim 11 (which recites a process of making the tablet) contain the limitation “*substance active sous forme de microcristaux ou microgranules enrobés*”. As in the other Romance languages, the adjectives in French agree in gender and number with the nouns to which they refer. One of the adjectives concordance rules states that when an adjective refers to a group of masculine and feminine nouns, only the masculine concordance rule applies. Therefore, under the form it appears in the limitation (*i.e.*, masculine, plural), the adjective “enrobés” (*i.e.*, coated) necessarily applies to both “microcristaux” (masculine, plural) and “microgranules” (feminine, plural). In other words, Applicant would like to point out that in the PCT application, the invention as defined by the claims is limited to embodiments where the “active substance is in a form of coated microcrystals or coated microgranules”.

Amendment has also been made (via the present Amendment and the February 5, 2008 Amendment) to claims 26, 31, 43-45 and 47, which have been amended to correct minor typographical errors and for improved clarity.

Rejection under 35 U.S.C. § 103

Claims 21-39 and 40-41 stand rejected under 35 USC § 103(a) as being obvious over Hunter *et al.* (U.S. Pat. No. 6,391,337) in view of Schmidt *et al.* (U.S. Pat. No. 6,079,968), and Valentine (U.S. Pat. No. 4,684,534). Claims 31 and 42-47 stand rejected under 35 USC § 103(a) as being obvious over Hunter *et al.* in view of Schmidt *et al.*

In the Final Office Action, the Examiner states that the Hunter *et al.* reference teaches pharmaceutical dosage forms for a rapidly disintegrating tablet, and processes for making this tablet. The Examiner further states that the tablets disclosed in Hunter *et al.* can comprise various saccharides, a lubricant, a disintegrant as well as other additives, such as flavorants, sweeteners, and coloring agents, and notes that these dosage forms are prepared by direct compression of a dry granulate. The Examiner concedes that the Hunter *et al.* patent does not explicitly teach methods of manufacturing tablets wherein the lubricant is entirely or mostly applied to the outer surface of the tablet, but cites the Schmidt *et al.* patent for its alleged

disclosure of a device that sprays powdered lubricants onto punches and dies of a tablet press and that can be readily retrofitted into existing machinery. The Examiner also cites the Valentine patent, as a teaching reference, which states that lubricants having a particle size of 44 microns or less are known and desired within the art of manufacturing tablets.

The Examiner has taken the position that it would have been obvious to one skilled in the art, at the time the invention was made, to combine the teachings of Hunter *et al.* and Schmidt *et al.* into the objects of the instantly claimed invention.

Applicant respectfully disagrees, and for reasons set forth below, respectfully submits that the Examiner has failed to show that the prior art references teach or suggest all of the claim limitations, as required to support a *prima facie* case of obviousness.

In particular, Applicant respectfully points out that the Examiner has overlooked the limitation (present in the claims as originally filed) which requires that the active substance comprised in the claimed tablet be in a form of coated microcrystals or coated microgranules. The Examples of the patent application describe, in particular, tablets comprising *coated microcrystals* of paracetamol (see Example 1), *coated ibuprofen granules* (see Example 2), and *coated aspirin granulate* (see Example 3). In contrast, in the tablet taught by the Hunter *et al.* patent, the active substance, *i.e.* acetaminophen in granular form, is NOT coated. Although Hunter *et al.* contemplate coating of the tablet itself (see, for example, column 14, lines 29-65), the Hunter *et al.* patent does not disclose or suggest a compressible tablet comprising an active principle that is enveloped by a coating, and more specifically that is “in a form of coated microcrystals or coated microgranules”.

Applicant would also like to point out that the presence of a coating enveloping the active substance automatically results in the active substance not being in direct contact with the tableting excipients (*e.g.*, disintegrant agent, soluble agent, and lubricating agent). This implicit feature further distinguishes the claimed tablet from the tablet described by Hunter *et al.* (be it modified or not using the teaching of Schmidt *et al.*), where acetaminophen, the active principle, is in direct contact with the excipients.

In light of the arguments put forward above, Applicant submits that Hunter *et al.*, taken alone or in combination with Schmidt *et al.*, and Valentine, do not teach or suggest all the limitations of the compressible tablet recited in independent claim 21, or of the process for making such a tablet as recited in independent claim 45, and therefore do not render obvious any claims of the instant application. Accordingly, Applicant respectfully requests that the rejection be reconsidered or withdrawn.

For at least the reasons set forth above, it is respectfully submitted that the above-identified application is in condition for allowance. Favorable reconsideration and prompt allowance of the claims are respectfully requested.

Should the Examiner believe that anything further is desirable in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number listed below.

Respectfully submitted,

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